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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,547	03/04/2002	Russell Morrison Evans III	VI/97-007.FWC.D.C.C.	7123

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EXAMINER	
SMITH, RUTH S	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,547	EVANS ET AL.	
	Examiner	Art Unit	
	Ruth S Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Applicant's election of the invention of Group I in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 21-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Information Disclosure Statement

The information disclosure statement filed 3/4/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The present application is not a continuation of all of the cited applications which contain copies of the references.

Specification

The abstract of the disclosure is objected to because it includes legal phraseology such as means plus function language. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: On page 1 of the specification, applicant should update the status of the continuing data. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-16, 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 13,20 define structure in terms of the patient, thereby including the patient as part of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**
> **(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.**

Claims 1-7,9-14,17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kampfe et al. Kampfe et al disclose a controlled angiographic injector device. The device is used with imaging of the patient. The imaging contrast agent can be x-ray, ultrasound or MRI. The device controls, the concentration, volume or flow rate of the injected contrast agent. The concentration is monitored and adjusted by means of an input device 44 coupled to a control unit 42. A diluent is mixed with the contrast medium in amounts to obtain a desired concentration. Elements 26,28,30 can comprise a vacuum pump or a peristaltic pump which comprises a pressurizing unit. The input means 44 provides a control unit adapted to adjust the condition of the injected contrast agent, the unit 42 provides an electronic interface. The device includes a fluid path between the patient and the pressurizing unit. Kampfe et al disclose a mixer 20 and a filter 46 disposed in the fluid path. Element 32 in combination with elements 26,28 provide a concentration measurement device.

Claims 1,2,4,6,7,10,11,13,17,20 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldstein. Goldstein discloses a microprocessor controlled angiographic injector device. The device is used with x-ray imaging of the patient. The device

controls, the pressure, volume or flow rate of the injected contrast agent. The control pad provides a control unit adapted to adjust the condition of the injected contrast agent, the CPU provides an electronic interface. The structure disclosed for delivering the fluid under pressure comprises a pump. The catheter provides a fluid path.

Claims 1,2,4,6,7,11,13,17,20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirschman et al. Hirschman et al disclose a processor controlled angiographic injector device. The device is used with x-ray imaging of the patient. The device controls, the pressure, volume or flow rate of the injected contrast agent. The I/O module provides a control unit adapted to adjust the condition of the injected contrast agent, the CPU provides an electronic interface. The structure shown in figure 5A for delivering the fluid under pressure comprises a pump. The syringe provides a fluid path.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3,14,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschman et al or Goldstein in view of Kampfe et al. Hirschman et al disclose a processor controlled angiographic injector device. Goldstein discloses a microprocessor controlled angiographic injector device. Goldstein and Hirschman et al fail to specifically disclose the use of a filter or an ultrasound contrast agent. Kampfe et al disclose the use of a filter in the fluid path to prove sterilization means for the system against bacteria. Kampfe et al further disclose that image contrast agents are known to be used with ultrasound in addition to x-ray. It would have been obvious to one skilled in the art to have modified either Hirschman et al or Goldstein to include a filter to prevent bacteria from entering the system as is a well known expedient in the art. Furthermore, it would have been obvious to one skilled in the art to have modified either Hirschman et al or Goldstein such that the contrast agent used is an ultrasound contrast agent. Such a modification merely involves the substitution of one known imaging modality for another.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kampfe et al, Hirschman et al or Goldstein. Kampfe et al disclose a controlled angiographic injector device. Hirschman et al disclose a processor controlled angiographic injector device. Goldstein discloses a microprocessor controlled angiographic injector device. Kampfe et al, Hirschman et al and Goldstein each fails to disclose the use of a hospital information system. Each of these references disclose the use of an operator controlled input device for inputting parameters into the system. In the absence of any showing of criticality or unexpected results, the type of parameters inputted into the system and the means used to input the parameters would have been a matter of ordinary engineering design choice of known functional equivalents in the art.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kampfe et al or Goldstein in view of Cornacchia et al. Kampfe et al disclose a controlled angiographic injector device. Goldstein discloses a microprocessor controlled angiographic injector device. Kampfe et al and Goldstein each fails to disclose the use

of back-flow valve in the fluid path. Cornacchia et al disclose a automated injection device for injecting a diluent in combination with a radionuclide into the body for imaging. Cornacchia et al disclose the use of a back-flow valve in the fluid path to prevent backflow of the radionuclide into the saline line. It would have been obvious to one skilled in the art to have modified either Kampfe et al, or Goldstein such that it includes a back-flow valve to prevent any of the contrast medium from flowing back into the line providing the diluent.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kampfe et al, Hirschman et al or Goldstein in view of Vaillancourt. Kampfe et al disclose a controlled angiographic injector device. Hirschman et al disclose a processor controlled angiographic injector device. Goldstein discloses a microprocessor controlled angiographic injector device. Kampfe et al, Hirschman et al and Goldstein each fails to disclose the use of a fluid assurance detector. Vaillancourt discloses an infusion delivery system having means for detecting the presence of air bubbles in the delivery line. It is old and well known that bubbles in the line can be harmful to the device and the patient. It would have been obvious to one skilled in the art to have modified Kampfe et al, Hirschman et al or Goldstein such that it included a bubble detector. The advantage of such is to prevent undesired harm from coming to the patient or device. A bubble detector comprises a type of fluid assurance detector.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Ruth S Smith
Primary Examiner
Art Unit 3737

RSS
May 27, 2003